

CRITERIA FOR PRIOR AUTHORIZATION**Calcimimetic Agents**

PROVIDER GROUP Pharmacy
Professional

MANUAL GUIDELINES The following drug requires prior authorization:
Cinacalcet (Sensipar®)
Etelcalcetide (Parsabiv®)

For all agents listed above, the preferred PDL drug, if applicable, which covers that specific indication, is required unless the patient has a documented clinical rationale for using the non-preferred agent, which is supported by the label.

CRITERIA FOR SENSIPAR® (cinacalcet)

- **TREATMENT OF SECONDARY HYPERPARATHYROIDISM** (Must meet all of the following):
 - Patient must have a diagnosis of chronic kidney disease
 - Patient is on dialysis (hemodialysis or peritoneal dialysis)
 - Patient must be 18 years of age or older
 - Current serum calcium is ≥ 8.4 mg/dL
 - Current iPTH (intact parathyroid hormone) levels are ≥ 300 pg/mL
 - Patient must have experienced an inadequate response after a trial of an oral or injectable vitamin D analog and a trial of an oral or injectable calcitriol agent at a maximum tolerated dose, OR have a documented intolerance or contraindication to treatment with oral or injectable vitamin D analog and calcitriol
 - Prescriber must provide chart notes documenting the patient's clinical assessment and history of all prior therapy trials including dates and outcomes of trials
- **CRITERIA FOR TREATMENT OF HYPERCALCEMIA IN PATIENTS WITH PARATHYROID CANCER** (Must meet all of the following):
 - Patient must have a diagnosis of parathyroid carcinoma
 - Patient must be 18 years of age or older
 - Patient must have hypercalcemia
 - Current serum calcium levels ≥ 10.2 mg/dL
- **CRITERIA FOR TREATMENT OF PRIMARY HYPERPARATHYROIDISM WITH SEVERE HYPERCALCEMIA** (Must meet all of the following):
 - Patient is unable to undergo parathyroidectomy
 - Patient must be 18 years of age or older
 - Current serum calcium is ≥ 12.5 mg/dL

RENEWAL CRITERIA FOR SENSIPAR® (cinacalcet)

- Patient must have one of the following
 - Diagnosis of chronic kidney disease and on dialysis (hemodialysis or peritoneal dialysis)
 - Parathyroid carcinoma
 - Primary hyperparathyroidism
- Current serum calcium is ≥ 7.5 mg/dL
- Current iPTH (intact parathyroid hormone) levels are ≥ 150 pg/mL

LENGTH OF APPROVAL FOR ALL INDICATIONS: 12 months

DRAFT PA CRITERIA

CRITERIA FOR PARSABIV® (etelcalcetide)

- **TREATMENT OF SECONDARY HYPERPARATHYROIDISM** (Must meet all of the following):
 - Patient must have a diagnosis of chronic kidney disease
 - Patient is on dialysis (hemodialysis or peritoneal dialysis)
 - Patient must be 18 years of age or older
 - Current serum calcium is ≥ 8.4 mg/dL
 - Current iPTH (intact parathyroid hormone) levels are ≥ 300 pg/mL
 - Patient must have experienced an inadequate response after a trial of an oral or injectable vitamin D analog and a trial of an oral or injectable calcitriol agent at a maximum tolerated dose, OR have a documented intolerance or contraindication to treatment with oral or injectable vitamin D analog and calcitriol
 - Patient must have experienced an inadequate response after a trial of Sensipar (cinacalcet) at the maximum tolerated dose, OR have a documented intolerance or contraindication to treatment with Sensipar (cinacalcet)
 - Prescriber must provide chart notes documenting the patient's clinical assessment and history of all prior therapy trials including dates and outcomes of trials

RENEWAL CRITERIA FOR SENSIPAR® (cinacalcet) AND PARSABIV® (etelcalcetide)

- Patient must have a diagnosis of chronic kidney disease
- Patient is on dialysis (hemodialysis or peritoneal dialysis)
- Current serum calcium is ≥ 7.5 mg/dL
- Current iPTH (intact parathyroid hormone) levels are ≥ 150 pg/mL

LENGTH OF APPROVAL: 12 months

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

DATE

DATE

TABLE 1. PRIOR THERAPIES

VITAMIN D ANALOGS/CALCITRIOL
Calcifediol
Calcitriol
Cholecalciferol
Doxercalciferol
Ergocalciferol
Paricalcitol